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REPORT

United Kingdom Patent Decisions 2016

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Abstract This report highlights the main UK patent cases from 2016, including the interpretation of "plausibility" and "obvious to try", obviousness, experimental use, numerical limits, infringement, stays, and a case to watch on "Arrow declarations".

Keywords Arrow declaration · Experimental use · Obvious to try · Obviousness · Patent law · Plausibility

Legislation Patents Act 1977 (UK).

Cases *Accord Healthcare Ltd v. Medac Gesellschaft fur Klinische Spezialpraparate mbH* [2016] R.P.C. 17; *Actavis UK Ltd v. Eli Lilly & Co* [2014] All E.R. 331; [2016] All E.R. 666; [2016] EWHC 234 (Pat); *Actavis Group PTC EHF v. ICOS Corp* [2016] EWHC 1955 (Pat); *Apotex Pty Ltd v. Warner-Lambert Co LLC (No 2)* [2016] FCA 1238; *Arrow Generics Ltd v. Merck & Co Inc* [2007] EWHC 1900 (Pat); [2016] EWHC 2204 (Pat); [2016] EWHC 3383 (Ch); *Dyson Appliances Ltd v. Hoover Ltd* [2002] R.P.C. 22; *Eli Lilly & Co v. Janssen Sciences Ireland UC* [2016] EWHC 313 (Pat); *Fujifilm Kyowa Kirin Biologics Co Ltd v. Abbvie Biotechnology Ltd* [2016] EWHC 425 (Pat); *Generics (UK) Ltd (t/a Mylan) v. Warner-Lambert Co LLC* [2016] R.P.C. 3.; *GlaxoSmithKline UK Ltd v. Wyeth Holdings LLC* [2016] EWHC 1045 (Ch); *Hospira UK Ltd v. Cubist Pharmaceuticals LLC* [2016] EWHC 1285 (Pat); *Hospira UK Ltd v. Genentech Inc* [2016] R.P.C. 1; [2016] EWCA Civ 780; *Idenix Pharmaceuticals Inc v. Gilead Sciences Inc* [2016] EWCA Civ 1089; *IPCom GmbH & Co Kg v. HTC Europe Co Ltd* [2014] R.P.C. 12; *Merck Sharp & Dohme Ltd v.*

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Shionogi & Co Ltd [2016] EWHC 2989 (Pat); *Meter-Tech LLC v. British Gas Trading Ltd* [2016] EWHC 2278 (Pat); *Napp Pharmaceutical Holdings Ltd v. Dr Reddy's Laboratories (UK) Ltd* [2016] EWHC 1517 (Pat); [2016] EWCA Civ 1053; *Richter Gedeon Vegyeszeti Gyar RT v. Generics (UK) Ltd (t/a Mylan)* [2016] EWCA Civ 410; *Schlumberger Holdings Ltd v. Electromagnetic Geoservices AS* [2010] R.P.C. 33; *Warner-Lambert Co LLC v. Generics (UK) Ltd (t/a Mylan)* [2016] EWCA Civ 1006.

Alongside the constant political intrigue over Britain's participation in the unitary patent and Unified Patent Court, domestic patent jurisprudence continued at pace throughout 2016. Ten of the more notable judgments of the year are extracted in this report.

As in 2015, litigation over Warner-Lambert's second medical use patent for pregabalin (branded Lyrica) generated significant decisions, in the UK and internationally. In October 2016, the Court of Appeal[1] upheld Arnold J's September 2015 decision[2] that claims to the use of pregabalin for treating pain and, in the alternative, neuropathic pain, failed for insufficiency because they were not plausible across their breadth.[3] This finding invalidated core claims in Warner-Lambert's infringement case against generics manufacturer Actavis. Given that an application to amend the claims post-trial was unsuccessful, there was no definitive ruling on infringement.

Delivering the Court of Appeal's judgment, Floyd LJ addressed the "plausibility" requirement that has acquired increasing prominence across sufficiency, industrial applicability and obviousness assessments, stating that it is a "low, threshold test … designed to prohibit speculative claiming".[4] It requires proof that a claim is more than merely speculative, but it should not be conflated with the test of "obvious to try". In dicta, Floyd LJ also reconfirmed his view on construction of "Swiss form claims", dismissing Arnold J's differing interpretation in earlier stages of the litigation.[5] Floyd LJ held that what is required is that the manufacturer knows or is able to foresee that there will be intentional use of the drug for the new medical indication. Generics manufacturers carry the (onerous) burden of taking "all reasonable steps in their power" to prevent the product from being used for the patented purpose.

Soon after the *Lyrica* case, the Court of Appeal issued its decision in *Idenix Pharmaceuticals Inc v. Gilead Sciences Inc*.[6] Plausibility was also at issue, in the context of obviousness as well as sufficiency. The Court held that a claim to a class of billions of compounds with anti-Flaviviridae activity was obvious, due to lack of evidence making such a technical contribution plausible.

In the domain of obviousness, the "obvious to try" test arose in *Hospira UK Ltd v. Genentech Inc*,[7] concerning formulation patents of the breast cancer drug

[1] *Warner-Lambert Co LLC v. Generics (UK) Ltd (t/a Mylan)* [2016] EWCA Civ 1006.

[2] *Generics (UK) Ltd (t/a Mylan) v. Warner-Lambert Co LLC* [2016] R.P.C. 3.

[3] *Contra Apotex Pty Ltd v. Warner-Lambert Co LLC (No 2)* [2016] FCA 1238 (where the evidence led to the exact opposite conclusion in Australia).

[4] *See* similar *GlaxoSmithKline UK Ltd v. Wyeth Holdings LLC* [2016] EWHC 1045 (Ch).

[5] *See* 47 IIC 189 (2016); doi:10.1007/s40319-016-0457-x.

[6] [2016] EWCA Civ 1089.

[7] [2016] EWCA Civ 780.

trastuzumab (branded Herceptin). The Court of Appeal affirmed the first instance decision[8] that the formulations claimed were obvious to any skilled team motivated to produce a stable dry formulation, embarking on a standard screening programme, and using standard products. It was not necessary to show that the team knew, or "would" necessarily have arrived at, the precise formulation claimed. Floyd LJ stated that such a requirement would be a "wholly unrealistic" straightjacket on the law on obviousness, in a situation where there were a range of obvious possibilities, all of which could be arrived at without inventive effort. By contrast with *Hospira v. Genentech*, a case involving a compound that would not have been expected, and was therefore not obvious, was *Actavis Group PTC EHF v. ICOS Corp* (tadalafil).[9]

A short decision on obviousness was *Richter Gedeon Vegyeszeti Gyar RT v. Generics (UK) Ltd (t/a Mylan)*,[10] Sir Robin Jacob's final decision in his post-retirement capacity as occasional sitting judge. The question was whether a dosage patent for an oral contraceptive was invalidated by prior art reporting the trial of a 1.5 g dose. Such a dose was clearly too large to be credible, but the patent could be read, without invention, as disclosing the more relevant number of 1.5 mg. The Court of Appeal held that it was obvious that the skilled person would arrive at the correct dose simply by consulting another scientist.

The test case of *Actavis UK Ltd v. Eli Lilly & Co* (pemetrexed)[11] returned to the Patents Court for another decision by Arnold J, who had granted declarations of non-infringement in 2014 for pemetrexed in a saline reconstitution,[12] before being overturned in 2015.[13] Actavis modified its claim, to pemetrexed in a non-saline (dextrose) reconstitution, and again sought declarations. Arnold J accepted the application, noting various steps that Actavis had taken to prevent the product being reconstituted in saline (e.g. in instructions to consumers, and in processes and advice to hospitals and relevant authorities), and also noting the absence of persuasive evidence by Eli Lilly questioning the effectiveness of those steps.

In *Accord Healthcare Ltd v. Medac Gesellschaft fur Klinische Spezialpraparate mbH*,[14] the Patents Court distinguished the facts from *Schlumberger Holdings Ltd v. Electromagnetic Geoservices AS*,[15] which held that the person skilled in the art is not necessarily constant between the tests of sufficiency and inventive step. Birss J held that Medac's invention was not "art changing", and the skilled team was the same between sufficiency and inventive step. In relation to inventive step, Birss J emphasised a passage from the 2001 authority of *Dyson Appliances Ltd v. Hoover*

[8] [2016] R.P.C. 1.

[9] [2016] EWHC 1955 (Pat).

[10] [2016] EWCA Civ 410.

[11] [2016] EWHC 234 (Pat).

[12] [2014] 4 All E.R. 331.

[13] [2016] 4 All E.R. 666; *see* 47 IIC 189 (2016); doi:10.1007/s40319-016-0457-x.

[14] [2016] R.P.C. 17.

[15] [2010] R.P.C. 33.

Ltd,[16] quoted approvingly in *Schlumberger*: "the combined skills (and mind-sets) of real research teams in the art is what matters".[17]

In a case to watch in 2017, biosimilars manufacturer Fujifilm generated significant interest by applying for an "Arrow declaration" against AbbVie, producer of the blockbuster autoimmune drug, adalimumab (branded Humira).[18] First postulated a decade ago in *Arrow Generics Ltd v. Merck & Co Inc*,[19] though rarely granted, an Arrow order would declare that Fujifilm's products (dosing regimens of adalimumab) can never infringe AbbVie's divisional patents granted on the same products, on the basis that the alleged infringement would be either old or obvious. The actions move to substantive considerations in 2017, bringing particular scrutiny to AbbVie's management of its patent portfolio and its use of cascading divisionals.

It is worth mentioning *Meter-Tech LLC v. British Gas Trading Ltd*,[20] which involved a rare assessment of the "experimental use" defence to patent infringement. Deputy Judge Daniel Alexander QC held that the deployment of 120 smart metering systems was of a quantity that may have constituted experimental use in other circumstances. However, given that the systems were installed for the purpose of assessing customer satisfaction regarding installation time and usability, rather than to bring about adaptation and improvement to the technology, this did not amount to experimental purposes relating to the subject-matter of the invention.

In *Eli Lilly & Co v. Janssen Sciences Ireland UC*,[21] Rose J applied the Court of Appeal's 2013 guidance in *IPCom GmbH & Co Kg v. HTC Europe Co Ltd*,[22] concerning the granting of stays pending concurrent EPO validity proceedings. Eli Lilly has an ongoing application to contest Janssen's divisional patent and seek declarations of non-infringement in relation to its solanezumab antibody for Alzheimer's treatment. Despite an EPO appeal being imminent, with an opposition hearing scheduled four months after Rose J's decision, commercial certainty on validity and infringement in the UK were considered critical, with considerable value at stake for the parties and the public. Rose J concluded that the need for certainty warranted the refusal of a stay, allowing the cases to continue to develop in parallel.

Finally, on construction, *Napp Pharmaceutical Holdings Ltd v. Dr Reddy's Laboratories (UK) Ltd*[23] was a nice case on numerical limits, applying the general rule that claims specifying percentages should be rounded to the nearest whole

[16] [2002] R.P.C. 22.

[17] Also quoted with approval by Carr J in *Hospira UK Ltd v. Cubist Pharmaceuticals LLC* [2016] EWHC 1285 (Pat); and Arnold J in *Merck Sharp & Dohme Ltd v. Shionogi & Co Ltd* [2016] EWHC 2989 (Pat).

[18] *Fujifilm Kyowa Kirin Biologics Co Ltd v. Abbvie Biotechnology Ltd* [2016] EWHC 425 (Pat) (Henry Carr J); [2016] EWHC 2204 (Pat) (Arnold J); [2016] EWHC 3383 (Ch) (Henry Carr J, refusing an application to strike out).

[19] *Arrow Generics Ltd v. Merck & Co Inc* [2007] EWHC 1900 (Pat).

[20] [2016] EWHC 2278 (Pat).

[21] [2016] EWHC 313 (Pat).

[22] [2014] R.P.C. 12.

[23] [2016] EWHC 1517 (Pat); [2016] EWCA Civ 1053.

number. Because the patent expressed some elements in steps of 5%, the patentee tried to argue that the claim to 10% could cover amounts up to 15%. This was rejected in both the Patents Court and the Court of Appeal, with Floyd LJ stating that "a patent specification is not intended to be a puzzle game", and that patentees are welcome to state that figures are expressed to the nearest 5% if that is indeed in the case. A claim to "about 10%" allowed a marginally more generous degree of imprecision, of "9 to 11%".

On the legislative front, from 6 April 2017, the UK practice of allowing omnibus patent claims – i.e. those that refer generally to the description or drawings, rather than to technical features – will no longer be permitted, bringing national practice into line with European law.